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(57) Abstract: A composite surgical implant that is made of a sheet of a thermoplastic resin that includes a top surface, a bottom surface, and a surgical grade metal mesh or metal plate contained therein. The implant has one or more attachment structures that allow securement of the implant to a desired surface. The implant may be bent by hand, wherein upon the displacement of the implant, the implant will generally maintain the shape to which it has been displaced. Methods of manufacturing the implant are also provided.

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CRANIOFACIAL IMPLANT

FIELD OF THE INVENTION

Embodiments of the present invention relate generally to composite surgical implants, and more specifically, to surgical implants made of a planar sheet of a thermoplastic resin having a surgical grade metal mesh or metal plate contained therein. The implants may have one or more attachment structures that allow securement of the implant to a desired surface. The implant may also be bent by hand so that it generally maintains the shape to which it has been displaced.

BACKGROUND OF THE INVENTION

Craniofacial and especially orbital wall and floor defects may result from trauma, cancer, resection, or congenital defects. Such defects are typically treated surgically using bone grafts or synthetic implants. Congenital defects or fractures of the complex and relatively thin bone structures surrounding and supporting the human eye present difficult internal bone repair and fixation problems. In instances when the eye is subject to trauma, the margin or rim of the orbit may diffuse the force of the impact. However, compression of the orbital contents sometimes may occur and fracture the relatively fragile orbital floor and/or the lateral and medial orbital walls. Also injury at the lateral orbital rim may produce a fracture within the orbit. When the orbit is fractured standard bone-grafting techniques for orbital reconstruction may not result in predictable eye function and positioning. Often the support of the globe is deficient as a result of under correction of the defect, over correction, or inadequate reconstruction of the orbital volume. Further, the bone graft may be subject to resorption that may result in result in a less than optimal support. The accurate anatomical reconstruction of the bony orbit is essential to maintain normal function and appearance of the eye following orbital fractures. Because most of the bone of the internal orbital surfaces is thin, it is difficult to adequately stabilize the fractured bone fragments without the use of autogenous or alloplastic materials.

Damage to other craniofacial bones and the cranium may also occur from many of the above-listed sources, perhaps trauma and congenital defects being the most common. There are distinct needs to provide implants that can reconstruct or substitute for these bones to restore and maintain normal function and appearance.

Autologous bone grafts have been considered an optimal treatment method for orbital floor and wall reconstruction, as well as other craniofacial and cranial defects. However, this material is sometimes difficult to obtain and difficult to shape the bone graft material to properly fit within the orbit or other area to be reconstructed. For example, there are problems relating to the tissue donor site morbidity. As discussed above, autogenous bone grafts have frequently been used by craniomaxillofacial surgeons for the reconstruction of the internal orbit. Bone may be harvested from the calvarium and other autogenous materials including iliac bone or a split rib bone. Cartilage has also been used as a bone graft material. However, autogenous bones sometimes result in an unacceptable amount of resorption.

Accordingly, it is desirable to provide an improved implant for use in repairing and reconstructing craniofacial and cranial bones, as well as other non-weight bearing bones that may be damaged by trauma or other causes. A variety of alloplastic materials have been used for orbital reconstruction and craniofacial applications including, silicone rubber, Teflon® (manufactured by DuPont), Supramid® (manufactured by S. Jackson, Inc. based in Alexandria, VA), tantalum mesh, Vitallium® mesh, titanium mesh, polyethylene, and methyl methacrylate. Perforated biocompatible metallic strips and metallic panels may be used for rigid internal fixation of fractures in trauma surgery and as a plate material for bone immobilization and stabilization. Metal implants can be used for bone graft support material in reconstructive surgery.

Synthetic implant materials have the advantage of no donor site morbidity, ease of use, relative low cost and ready availability. While there are advantages of synthetic implants, some characteristics may be regarded as disadvantages. Silicone rubber has a smooth surface, but does not allow fibrovascular ingrowth into the implant. Further, although it is flexible, it does not readily conform to the profile of the region where it is required or maintain a new shape when shaped to fit a particular location. For example, in connection with the reconstruction of the orbit, a silicone rubber implant is not an attractive option because upon shaping it to the desired profile, it will tend to be biased back to its original shape. While a silicone rubber implant does not maintain its shape, in a case where the soft tissues of the orbit have been traumatized, an implant with a smooth superior surface is desirable to prevent attachment of the tissues to the implant upon

healing. Attachment of these tissues to the wall of the implant may result in restriction of movement of the eye, causing diplopia, dizziness, and headaches, as well as a cosmetic anomaly on upgaze, downgaze or lateral gaze.

Implants having a porous structure with predetermined pore sizes allow for fibrovascular ingrowth. In some circumstances, fibrovascular ingrowth is desirable because it integrates the implant within the tissues, and reduces the possibility that that the synthetic material will be rejected. Further, fibrovascular ingrowth on the inferior or sinus side of an orbital implant allows for mucosalization of the implant surface, and since the opposite side of the implant may be a barrier, the sinus is effectively isolated from the soft tissues of the orbit. Similar issues arise in connection with the repair of other craniofacial bones. This arrangement is considered desirable because it increases the ability of the implant to ward off infection and minimizes the chance of a sinus infection from entering into the orbit. Fibrovascular ingrowth is also thought to minimize the chance of implant migration or displacement. However, although some materials that are flexible and thin (appropriate for orbital floor and wall reconstruction) can be bent to an appropriate shape, the material tends to return to its original shape. Further, using a material that does not have a smooth superior surface, may result in restriction of the orbital tissues due to fibrous ingrowth when used for orbital reconstruction.

Pure titanium is the material of choice in craniofacial reconstructive surgery, especially when the implant is intended to be permanent. As an implant material, pure titanium is preferred because its low density and elastic modules are less than some of the stainless steel or cobalt-chromium alloys that have been used as implant materials. Titanium is corrosion resistant and, when provided in thin sheets, is pliable. Titanium implants many be cut and shaped to the appropriate configuration at the time of surgery. Titanium mesh is easily moldable in situ and easily fixed to bone, but does not have smooth surfaces, nor does it allow for fibrovascular ingrowth. An easily molded material is desirable for use in connection with embodiments of the present invention so that the surgeon can create the correct shape to properly reconstruct the orbital walls or orbital floor. Titanium mesh can be molded to the desired shape by hand and it will retain the shape due to the malleability and strength of the titanium material.

While there are a number of options for an implant material for orbital and other craniofacial reconstruction, there remains a need for a material that is easily moldable by hand and will retain its shape after molding, has options for surface smoothness or porosity, and is made from highly biocompatible materials. Preferably it is desirable to provide an implant that can be trimmed and bent to shape to fit the shape of the orbital wall or orbital floor reconstruction, and placed in the orbit with the smooth surface on the inside, against the periosteum and soft tissues and with the porous side directed toward the sinus region. Further, it would be desirable to provide a material that can be fixed to the orbital bones with surgical screws or to the surrounding tissues with sutures. It is also desirable to provide an implant having attachment structures that extend from the edges of the implant to assist with securement to the desired bone.

SUMMARY OF THE INVENTION

Embodiments of the present invention are directed to an improved implant and method of reconstruction of craniofacial defects, including cranial defects and orbital defects. Various embodiments of the implant comprise a composite structure comprised of a surgical grade metal provided in a planar or curved sheet form that is encased within a malleable biocompatible material, such as a polyolefin (e.g., polymers and copolymers of the ethylene family of hydrocarbons) like high density polyethylene. The polyolefin may either have a smooth surface or a interconnected open pore structure.

In a first embodiment, one surface of the implant is smooth and impervious so that when the implant is placed within the body, it may form a barrier. In an alternative embodiment of the invention, while one side of the implant has a smooth surface, the opposite side of the implant is comprised of a polyolefin porous surface, such as a porous polyethylene, that allows for fibrous tissue ingrowth. In a further embodiment, both sides of the implant have a polyolefin porous surface, such as a porous polyethylene, which provides an implant with both sides that allow fibrous tissue ingrowth. Embodiments of the implant also feature one or more attachment structures. The attachment structures may extend from the periphery of the implant and are intended to receive any appropriate fixation device to secure the implant to the desired surface.

In one embodiment of a method of reconstruction, the implant is cut and then shaped to conform to the profile of a defect to be treated. The implant is then secured to bony tissue using surgical screws or any other appropriate alternative fastening method, specifically using the attachment structures. In a particularly preferred embodiment, at least a portion of the implant comprises a mesh, allowing the implant to be malleable, while also maintaining its shape.

Accordingly, the present invention provides a unique implant for the repair of orbital defects, fixation of orbital fractures, and repair of other craniofacial and cranial defects.

The present invention further provides a unique composite implant structure which can be shaped for use during a surgical procedures relating to the repair or fixation of the desired bones, and be readily cut, reshaped or bent to conform to the bones to be repaired. In a particular embodiment, the present invention provides an implant that can be used to repair the orbital walls and can be affixed to the orbit or the orbital margin.

In another aspect, the invention provides an implant structure that forms a barrier between the sinus and the soft tissues of the orbit.

In a further aspect, the invention provides an implant that may be used in other applications (such as for other craniofacial and cranial applications or any other applications where bone may need to be repaired or fixed) in which it is desirable to maintain the shape of the implant or form the implant into a desired shape.

Other objects and advantages of the invention will be apparent from the following summary and detailed description of the orbital repair implant structure of the invention taken with the accompanying drawing figures.

One aspect of the invention relates to a composite surgical implant comprising

(a) a top surface and a bottom surface, each surface comprising a layer of a polyolefin material,

(b) a surgical grade metal mesh contained between the top and bottom surfaces, and

(c) one or more attachment structures adapted to attach the implant to a desired surface,

the implant being bendable or displaceable by manipulation by hand, wherein upon the displacement of the implant, the implant will generally maintain the shape to which it has

been displaced. The surgical grade metal mesh may comprise titanium, surgical grade stainless steel, steel coated with titanium, titanium nitride, titanium alloyed with other metals, composites of any of the above materials, or any combination thereof. It may further comprise wire screen, expanded metal, perforated metal sheet, perforated bars, an interconnected meshwork of perforated bars, a grid, a free form solid, a perforated or machined shaped sheet, or any combination thereof.

The polyolefin material may comprise polyethylene, high density polyethylene, ultra high molecular weight polyethylene, polyether ether ketone, thermoplastic resins, polyethylene terephthalate, nylon, any polymer of aliphatic hydrocarbons containing one or more double bonds, composites of any of the above materials, or any combination thereof.

In one embodiment, the top surface, the bottom surface, or both surfaces comprise a smooth barrier surface. In an alternate embodiment, the top surface, the bottom surface, or both surfaces comprise a porous surface. If provided, the porous surface may have pores that are sized to allow for fibrovascular ingrowth.

The attachment structures may be provided in many different forms. They may be openings in the mesh that receive and engage a head of a surgical screw or surgical bone anchor, one or more strands of rings that are adapted to receive a fixation device, or one or more angled brackets.

The implant may be provided in a particular shape to approximately fit a particular surgical site. The implant may also include cells or biologically active molecules.

In a further embodiment, the implant comprises openings, grooves, or channels that are adapted to accommodate nerves or vessels that may lie underneath the implant during use.

The implant may be provided in a kit of implants having varied features, for example, one or more of varied thicknesses, mesh patterns, strengths, sizes, shapes, malleability, seeding options, or combinations thereof.

In other embodiments, the metal mesh is sized to allow load bearing reconstructions of the mandible or long bones. In other embodiments, the polyolefin material provides volume filling capacity for resected or deficient bony structures, and

provides a smooth surface over the metal component to minimize the possibility of implant exposure through the skin or soft tissues.

Another aspect of the invention relates a method of making a surgical implant comprising:

(a) placing a metallic mesh material having a body portion and an attachment structure portion over a cavity in a lower portion of a mold, such that the attachment structure portion rests on a ledge; and

(b) introducing thermoplastic resin fines into the cavity portion of the mold to allow the fines to fill the lower portion of the mold and the interstitial spaces of the body portion of the mesh.

If a barrier is desired on one side of the implant, the method may further comprise:

(c) placing a sheet of thermoplastic resin over the fines and the mesh;

(d) placing a mold top over the sheet and applying heat and pressure to the components contained in the mold to allow the fines to partially melt and to fuse to one another,

whereby an implant is constructed having a smooth barrier surface and an opposite porous surface.

If a barrier is desired on both sides of the implant, the method may include placing a thin barrier sheet on the bottom surface of a cavity of the mold, whereby the implant created comprises barriers on opposite sides of the mesh.

Further aspects of the invention relate to a method of reconstruction of a bone defect comprising,

(a) bending a surgical implant having a top and bottom surface comprised of a polyolefin material, a metallic mesh embedded in the material to conform to the profile of the defect, and one or more attachment structures extending from the implant; and,

(b) mechanically attaching the implant to bone in proximity with the defect using the attachment structures that extend from the implant.

The defect being treated may be in the cranium, the orbit, the mandible, any craniofacial bone, or on any other bone that may be treatable using the implants described herein.

If treating a cranial defect, a particular implant may comprise a top smooth barrier surface and a bottom porous surface and the implant is positioned over a cranial defect with the top smooth barrier surface oriented away from the defect.

If treating an orbital defect, a particular implant may comprise a top smooth barrier surface and a bottom porous surface and the implant is positioned in the orbit with the top smooth barrier surface oriented toward the orbital defect.

The attaching step can comprise introduction of mechanical fasteners, such as screws, through the attachment structures and into the bone. In one embodiment, the implant may be cut to conform to the shape of the defect.

A further aspect of the invention provides a kit for the repair of a bone defect, comprising

(a) one or more surgical implants comprising a top surface and a bottom surface, each surface comprising a layer of a polyolefin material and a surgical grade metal mesh contained between the top and bottom surfaces, the surgical implant further comprising one or more attachment structures adapted to attach the implant to a desired surface, the implant being bendable or displaceable by manipulation by hand; and

(b) one or more aids for shaping the implant.

The surgical implants can be provided in one or more different sizes, shapes, or thicknesses and/or having one or more different attachment structures. The aids for shaping the implant may be a clear template of the implant shape. The kit may also include scissors for cutting the template or trimming the implant and or instructions for the use of the implant.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top plan view of a first embodiment of an implant according to the invention wherein the top side of the implant is a barrier surface.

FIG. 2 is a side view in elevation of the first embodiment of the invention showing the barrier surface and the bottom porous surface.

FIG. 3 is a bottom view of the first embodiment of the invention.

FIG. 4 is a perspective view of the first embodiment of the invention.

FIG. 5 is a side sectional view of an implant within one embodiment of a mold.

FIG. 6. is a top view of a mold depicted in FIG. 5 with the top cover removed.

FIG. 7 is a top view of an alternative mold that can be used to create the implant with the top cover removed.

FIG. 8 is a side sectional view of the mold depicted in FIG. 7

FIG. 9 is a top view of titanium mesh that may be employed with any of the embodiments of the invention.

FIG. 10 is an enlarged view of a section of the titanium mesh depicted in FIG. 9.

FIG. 11 is a side sectional view of an implant having opposite barrier surfaces on either side of a center section.

FIG. 12 is a side view in elevation of the implant depicted in FIG. 11.

FIG. 13 is a side sectional view of the implant depicted in FIGS. 1-3.

FIG. 14A depicts a sectional view of a cranial defect.

FIG 14B depicts a cranial defect with one embodiment of a cranial implant in place.

FIG. 15 is a side sectional view of the implant shown in FIGS. 1-3 within a cranial defect.

FIG. 16 is yet another embodiment of the invention wherein the implant has opposite barrier surfaces.

FIG. 17 is a side view in elevation of the implant depicted in FIG. 16.

FIG. 18 is a side sectional view of a further embodiment of the invention wherein the metal mesh is formed with an implant with opposite porous surfaces.

FIG. 19 is an exploded view of an implant having three layers.

FIG. 20 is a perspective illustration of an implant according to the invention shown in an orbital floor reconstruction application.

FIG. 21 is a top plan view of one embodiment of an orbital reconstruction implant with attachment structures.

FIG. 22 is a top plan view of a cranial implant made according to certain embodiments of the invention.

FIG. 23 shows an implant with a series of alternate attachment structures.

FIG. 24 shows a burr hole cover embodiment.

FIG. 25 shows one embodiment of a mold that may be used to create an implant having attachment structures and a barrier layer.

FIG. 26 shows one embodiment of a mold that may be used to create an implant having attachment structures and a porous layers on both sides of a mesh.

FIG. 27 shows an example of a top view of a mold with the top cover removed that may be used to create an implant having attachment structures as shaped in FIG. 21.

DETAILED DESCRIPTION

The present invention is directed to novel implants for craniofacial surgery, methods for making said implants, and methods of reconstructing orbital, cranial and craniofacial defects with the implants described. As described herein, one preferred application for the implant is for the reconstruction of orbital defects, such as those that may have resulted from trauma, disease or birth defects. Other craniofacial and cranial applications are also contemplated. The implants preferably have a mesh portion that is coated or covered with a smooth (or barrier) sheet on both sides of the mesh, a porous sheet on both sides of the mesh, or a smooth (or barrier) sheet on one side of the mesh and a porous sheet on the other side of the mesh.

A first embodiment of the invention comprises a sheet of mesh with a porous layer formed in the interstices of the mesh and at least partially or completely covering the bottom surface of the implant, and a solid sheet of film covering the top side of the implant. This embodiment allows tissue ingrowth on the porous side and prevents tissue ingrowth on the solid film side.

The mesh provides for strength and serves to retain the shape of the implant in a rigid and fixed position. It should be understood that a mesh as used herein may encompass any flat or curved sheet of surgical grade metal that has perforations or passages formed through the sheet. The passages in the sheet help enable the sheet to be shaped or bent in more than one dimension and then retain the desired shape. It is contemplated that the mesh could be formed in a variety of manners including woven screens, etched from plates, formed from solid plates that are cut and then expanded to form a substrate having passages.

The first specific embodiment of the invention is illustrated in FIG. 1 where a solid smooth barrier material 23 lies on top of the mesh material 20 with porous material

25 formed in the interstices and under the mesh 20, and at least partially or completely covering the bottom surface 27 of the implants, as shown in FIGS. 2 and 3. As best seen in FIG. 4, the top surface 23 of the implant preferably has some transparency so that the mesh 20 may be seen through the polyethylene film layer 23. While FIG. 1 shows the mesh extended to the periphery of the implant, it is contemplated that in some embodiments the mesh may not extend to the edge of the implant structure. In yet other embodiments, the mesh may extend from the implant structure. In this later regard, it may be advantageous to extend the mesh from the implant structure to provide for a projection to be employed for the attachment of the implant during the surgical procedure, an option that is described in more detail below. The mesh as described throughout this application is preferably titanium, although other materials are considered within the scope of this invention, non-limiting examples of which are provided below.

FIG. 13 shows a side sectional view of the implant depicted in FIGS. 1-4 with the mesh 20 formed along the interface 175 between the porous layer and the solid polyethylene layer 23.

FIG. 11 depicts yet another embodiment of the invention in which the mesh 150 is placed between two opposite polyethylene barrier sheets 153 and 155. This embodiment prevents tissue ingrowth on both sides of the implant. A porous matrix 160 may optionally be sandwiched between the barrier sheets 153 and 155. The configuration of this implant provides a bendable sheet that has a smooth polyolefin (e.g., polyethylene) surface on both the top and bottom surface. The implant will retain its shape after it has been bent to conform to the contours of defect to be treated. The thickness of the sheets of polyethylene may be selected to result in an implant having the desired thickness, while also retaining the desired malleability or flexibility. In the alternative, the thickness of the implant may be adjusted by variation of the porous matrix layer 160. Like the previous embodiments, the implant may be bent by the surgeon and it will maintain its shape.

In yet a further alternative embodiment of the invention, the structure comprises a mesh plate (preferably titanium, although other materials are considered within the scope of this invention) within a porous matrix (preferably a polyethylene matrix, although other materials are considered within the scope of this invention) wherein all sides have

porous surfaces. FIG. 18 depicts a sectional view wherein the mesh 300 is formed with a porous polyethylene matrix. This implant may be suitable for those applications where a smooth barrier surface is not indicated. For example, an implant having porous surfaces that allow for fibrovascular ingrowth on opposite sides may be particularly indicated in cranial applications and for temporal implants for soft tissue replacement, although such implants may be used for any other appropriate procedures or indications.

Temporal implants for soft tissue replacement is intended to refer to implants that may be used to replace the thick temporalis muscle that covers the temporal area of the cranium. This muscle is sometimes used as a pedicled flap to repair soft or hard tissue defects in the craniofacial area. For example, if a tumor is removed from the roof of the mouth, the temporalis muscle may be lifted from the cranium with one end still attached to its blood and nerve supply. The other end is moved into the defect in the roof of the mouth. This results in a soft tissue defect in the temporal area. Implants according to various embodiments of this invention may be used to fill this defect. (In other words, they are typically attached to the cranial bone, but they do not correct a bony defect, just the temporal soft tissue defect.) In other instances, the temporalis muscle may be cut through when performing a pterional craniotomy, where the cranial bone under the temporalis muscle is temporarily removed to gain access to the brain. Although the bone is replaced, the temporalis muscle will atrophy, resulting in a temporal soft tissue defect. Implants according to various embodiments of this invention may be used in this regard as well.

FIG. 16 depicts yet a further embodiment of the implant wherein the top surface 214 and bottom surface 216 are polyethylene sheets. This embodiment differs from that shown in FIG. 11 because it does not contain an inner porous matrix sandwiched between the sheets. The mesh 220 is contiguous with the internal surfaces of both the top sheet 214 and the lower sheet 216. This implant has a top barrier surface 221 and bottom barrier surface 223 and is indicated in those applications where fibrovascular ingrowth is not desired.

FIG. 19 shows an exploded perspective schematic view of one embodiment according to the invention. Top layer 400 may comprise a barrier surface or porous surface. The mesh 405 may be any metallic material suitable for surgical applications and

is malleable and will retain its shape. Bottom layer 410 may be a barrier surface or a porous surface. This embodiment depicts mesh 405 at the interface between the layers 400 and 410.

In any of the above-described configurations, the mesh is preferably comprised of titanium, although it should be understood that the mesh may comprise surgical grade stainless steel, steel coated with titanium, titanium nitride, titanium alloyed with other metals to adjust the physical properties of the metal as needed for the particular applications, composites of any of the above materials, or any other appropriate material that will allow the implant to be at least partially pliable, while also maintaining its structural integrity.

In another embodiment of the invention, it may be desirable to impart shape memory to the implant by using a metal that returns to its shape when bent. For instance, in endoscopic procedures to repair an orbital floor defect, a thin sheet implant, cut slightly larger than the defect, may be pushed through the defect from the maxillary sinus side. Using a flexible but springy sheet would allow the implant to return to is preformed shape after flexing it enough to push it through the defect, thus allowing the surgeon to repair the defect from the maxillary sinus without entering the orbit from outside the body. In the current state of the art, this is accomplished with porous or solid polymer sheet, but using a metal mesh with shape memory characteristics could allow for larger, stronger, or thinner implants for this purpose.

The metal component of the invention could comprise wire screen, expanded metal, perforated metal sheet, perforated bars, an interconnected meshwork of perforated bars, a three dimensional grid, including rectangular, square triangular, or any appropriate cross section of grid design, a free form solid, a perforated or machined shaped sheet, or any combination thereof. The metal component may have openings ranging from none to large free form openings. The metal surfaces may be smooth or irregular, including irregular surfaces which improve the attachment of the polymer component to the metal component. (As described above, any of the metal components described here may be enveloped in porous polymer, porous polymer with one or more barrier surfaces, or with solid smooth polymer.) Methods for fabricating the metal component include, but are not

limited to, machining from stock metal, acid etching, EDM (electrode deposition machining), laser cutting, water jet machining, selective laser sintering, perforating and expanding metal sheet, or any other method known to the art.

In a particular embodiment of the invention, the metal components may be designed to support load bearing structures in the body, such as in the mandible or in long bone fracture repair. The polymer component provides a smoother, lighter, void filling material which allows vascularization by the body. For example, when full thickness portions of the mandible are resected to remove a tumor, the mandible is often reconstructed by bridging the gap with a load bearing metal fixation plate.

Previously-used plates are typically 2 mm thick, 9 mm tall, long enough to bridge the defect, with evenly spaced holes to accept screws to allow fixation to the remaining portions of the mandible, but without a polymer cover. These plates are subject to erosion through the surrounding or overlying tissues. Furthermore, they do not fill the void left by the resected bone, leaving a void in the tissues. By embedding a fixation plate of this type in a polymer structure (such as a high density polyethylene), the resulting implant can be shaped to fill the bony defect, and can be made with a smoother surface that tapers gently to the remaining bone, reducing the probability that the plate will erode through the surrounding tissues. The polymer component of the implant can be made to allow the polymer to be carved in the operating room to the appropriate size and shape to fit the defect created by the resection procedure. The metal portion provides the necessary load bearing property to effect a permanent repair, while the polymer portion restores natural contour to the skeleton.

In a preferred embodiment, the porous layer is comprised of a polyolefin and even more preferably, a polyethylene such as high density polyethylene that either has an interconnected pore structure (referred to as "porous") or a smooth non-porous structure (referred to as "smooth"). One potential polyethylene is ultra high molecular weight polyethylene (UHMWPE). Other potential materials may be high density polyethylene, low density polyethylene, linear low density polyethylene, very low density polyethylene, ethylene-vinyl acetate copolymers, ionomers, cross-linked polyethylene, or combinations thereof.

Alternatively, the layer may comprise polyether ether ketone (PEEK), polyethylene terephthalate (PETE), nylon, polypropylene, or any polymer made of aliphatic hydrocarbons containing one or more double bonds before polymerization, composites of any of the above materials, or any other appropriate material that can be bent or otherwise formed to cover the mesh, and allow the implant to be at least partially pliable, while also imparting the desired porosity.

One embodiment of the invention provides structures that can be used to attach the implant to the desired surface. FIG. 21 shows an orbital implant 200 having attachment structures 202 extending from the periphery 204 of implant 200. In this embodiment, attachment structures 202 are shown as a series of four circular rings 206, although it should be understood that attachment structures 202 may take on any form that allows them to receive any appropriate fixation device (such as a screw, a tack, a pin, a surgical nail, and so forth). For example, attachment structures may be square or rectangular shaped, oblong, triangular, trapezoidal, or any other appropriate shape. They may also be provided in any number, such as one, two, three, four, ten, twenty, or any other desired number. They may also be any length that is appropriate for the site of insertion and the degree of attachment required.

Additionally, although attachment structures 202 are shown in groups of multiple strands 208 (i.e., one group of four strands and another group of two strands, the term "strands" being used to refer to a strip of the structures), it should be understood that structures 202 may provided in any number of strands 208 and in any configuration or combination. For example, a single implant could have a single strand of rings in one place, a triple strand of squares in another place, and/or evenly spaced strands in other places. In other words, one or multiple strands having one or multiple shapes (in any combination) may extend from implant 200 in groups, in strategically placed locations, or randomly along the periphery 204. It should be understood that providing multiple attachment structures 202 provides the surgeon with more location options for securing implant 200 in place. In another embodiment, the attachment structures are simply a portion of the mesh that is allowed to protrude beyond the polyethylene and/or barrier surfaces that are formed on either side.

Attachment structures 202 may be placed in certain areas where it is envisioned that attachment may optimally take place. Any attachment structures 202 that are not used may optionally be trimmed or clipped from implant 200 to prevent them from interfering with the surgical site and/or the healing process. The attachment structures 202 described in this section may be used in connection with any of the implant embodiments described herein.

While in the embodiments depicted herein, the mesh is depicted in the center of the implant structure, it is contemplated that the mesh may be positioned adjacent to the top thin sheet layer or other locations within the implant depending on the respective application.

Now referring to FIG. 5, to manufacture the implant as depicted in FIG. 1, a mesh 40 is selected and positioned on tabs 50 that project from the sidewalls 45 and 48 of the bottom of the mold section 42. Next, polyethylene fines are introduced into the mold so that they fill the void below the mesh 40, the spaces between the titanium mesh 40 and cover the top surface of mesh 40. Last, a thin sheet or continuous film of solid polyethylene 55 is placed on the top of a suitable mold. The solid barrier sheet 55 extends beyond the edges of the cavity section of the mold and extends to the mold surface 63 thereby maintaining the sheet on one side of the mold.

FIG. 5 is a sectional view of the implant according to the invention located within a mold. As depicted therein, the mesh is located adjacent to the barrier layer on the top of the mold. The barrier layer is formed of a solid sheet of polyethylene and the porous section is made by sintering together polyethylene fines under heat and pressure. The solid sheet may be made by introducing polyethylene fines to a press having opposite smooth metal sheets and heating the surfaces causing the fines to completely fuse together. When the implant has cooled, the structure may be removed from the mold because both the tabs 50 and the implant material have some flexibility.

Now referring to FIG. 6, a contemplated arrangement depicting a plurality of tabs 50 provided on the lower section of mold 61 is shown. The mesh sheet will rest on or is supported by the tabs 50 provided around the periphery of the mold. The tabs are placed a distance from the top surface of the mold that is slightly less than the width of the mesh, so that when the top of the mold that retains the barrier sheet is placed over the mold

bottom, the thin barrier sheet may come into contact with the mesh. FIG. 7 depicts an alternative arrangement wherein the mold is provided with a shelf to retain the mesh in position near the top of the mold.

FIG. 7 depicts an alternative arrangement for a mold wherein the mesh may be received on a shelf 70 that is suspended over the cavity using a shelf 70 around the mold cavity that holds the mesh sheet in position. As best seen in FIG. 8, shelf region 70 that extends into the void area 78 of mold 75 supports the edges of the mesh. A polyethylene sheet 90 is positioned above polyethylene fines 92 that fill the cavity 78. The passages through the mesh are identified by reference number 82. It should be understood that the dimensions, including the depth of the cavity from top surface 85 of bottom mold section 75, and the length and width of the mold may be altered depending on the particular application intended for the implant.

As illustrated by FIG. 8, the fines 92 come into contact with both the smooth polyethylene sheet 90 and the mesh 80. Once the mold is filled as described above, the top section 98 is placed over the components and the materials are subjected to heat and pressure, as is known in the current art, to form a porous polyethylene material. The heat and pressure cause the fines to be sintered together and to affix the polyethylene sheet and titanium mesh. The resulting structure has titanium mesh embedded within a porous matrix and a solid smooth polyethylene film that is attached both to the titanium mesh and/or to the porous polyethylene structure. The sheet or film of polyethylene is impervious to water and serves as a barrier.

FIGS. 25 and 26 show embodiments of molds that may be used to manufacture an implant having attachment structures. It should be understood that these are exemplary molds only, and that molds having additional features may be used and are considered within the scope of this invention. The mold 250 of FIG. 25 has a lower portion 252 and an upper portion 254. As shown, a mesh 40 is selected and positioned on a ledge 256 on the lower portion 252 so that the attachment structures on the mesh are allowed to extend beyond the edges of the cavity section 258 of the mold. If an implant with a barrier sheet is to be formed, then the process as described above is followed. For example, polyethylene fines are introduced into the lower portion 252 of the mold 250 so that they fill the cavity 258 below the mesh 40, the spaces between the mesh 40, and cover the top

surface of the mesh 40. A thin sheet or continuous film of solid polyethylene 55 is placed on the top of the mold and can be made by introducing polyethylene fines to a press having opposite smooth metal sheets and heating the surfaces, causing the fines to completely fuse together.

If the implant should have a barrier portion on both sides, a thin barrier sheet may also be placed at the bottom of the cavity before the mesh is placed and the polyethylene fines are introduced.

If the implant is to have a porous portion on both sides of the implant, then a mold 260 as shown in FIG. 26 may be used. Mold 260 also has a lower portion 262 and an upper portion 264. The mesh 40 is placed on a ledge 266 as described above, and polytheylene fines are introduced into the mold through an opening or gate 268 in the top of the mold 260 so that they fill the cavity 270 below the mesh 40, the spaces between the mesh 40, and cover the top surface of the mesh 40. As shown in FIG. 26, the material is allowed to flow into an upper cavity 272 as well, to provide both sides having a porous surface. A primary goal in manufacturing an implant with attachment structures is to keep the attachment structures from being coated or covered with polyethylene.

FIG. 27 shows a top view of a specific mold 280 that may be used to create an implant having attachment structures shaped and configured as shown in FIG. 21. This mold has a lower portion 282 and an upper portion (not shown). Lower portion 282 has ledges 284 that are configured similarly to the way that attachment structures 202 are configured. It also has a cavity 286 that is shaped similarly to the body of the implant. When the mesh 40 is placed over the cavity 286 such that the attachment structure portions 202 of the implant rest on ledges 284, an upper portion of the mold (not shown) may be placed over the lower portion 282 to provide a clamp against the ledges 284 to prevent polyethylene fines from traveling into the ledges 284 and covering the attachment structures. The remaining portion of the method may be as described above. Although one embodiment of a specific mold is shown, it should be understood that any other configuration of attachment structures and ledges may be provided. For example, an implant may have more or fewer than the six attachment structures shown, and as such, the mold would have more or fewer ledges. The ledges will generally be situated in the locations where the attachment structures on the implant are situated.

An alternative method for manufacturing various implants is to coin curves into the implant for improved anatomic shapes. This is particularly useful because it is easier to make the composite implants described herein as a flat sheet of material rather than manufacture it as a curved design. However, there are many procedures for which the implant should be preferably pre-curved or pre-shaped so that it more accurately fits the bone to be replaced. Even though the implants are malleable by hand, it is still useful to provide implants that are pre-shaped. This can help reduce operating room time, because the implant is already generally shaped appropriately.

For example, a cranial implant may be provided with a rounded or dome shape so that it fits the cranium more precisely. An orbital implant may have a pattern that mimics the orbital floor or any other anatomical feature. The coining process generally entails taking a flat manufactured implant (metal mesh embedded in an polyolefin layer) and coining the desired shape into it by putting the implant into a mold and applying pressure so that the mold causes the implant to bend in the mold's shape. A heat cycle allows the polyolefin (e.g., polyethylene layers) to relax and bend into the desired shape.

In a preferred embodiment of the invention described above, the polyethylene film is approximately 0.1 mm thick, the titanium mesh is approximately 0.35 mm thick and the porous polyethylene is approximately 0.9 mm thick, inclusive of the imbedded titanium mesh. Thus the overall thickness of the material is approximately 1 mm. In another preferred embodiment the titanium is 0.35 – 1 mm thick, the polymer is 4-6 mm thick (this embodiment may be particularly useful for certain cranial repairs). In yet another embodiment the titanium is 1-3 mm thick, with polymer being 3-5 mm thick (this embodiment may be particularly useful for mandibular reconstruction).

In another embodiment of the invention, the titanium component rests at one surface of the porous or porous/barrier polymer component, to allow the metal component to rest securely against the bone, for better stabilization of the bone against the metal component which is screwed to the bone.

Also, for implants that may be used in non-load bearing situations, the polymer portion of any of the above embodiments of the implant can be fixed to the bone with screws which go through the polymer only, without using the metal component for implant fixation.

Now referring to FIG. 9, in a preferred embodiment of the invention, the titanium mesh consists of a series of annular rings 107 that are attached to adjacent annular rings by bridges 110 also made of titanium. As best seen in FIG. 10, the annular rings have countersunk holes 115 that will receive the head of surgical screw. This structure allows for flexibility of the titanium component within the implant and the countersunk holes allow for easy fixation of the implant to the bone using appropriately sized surgical screws. In a preferred embodiment of the invention, the titanium is of sufficient strength in relation to the thickness of the polyethylene components (the solid sheet and the porous matrix) so that the implant will hold its shape after being bent by the surgeon. It is therefore contemplated that during a surgical procedure the surgeon may bend the implant to conform to the shape of the defect that is being treated. In a preferred embodiment the surgeon can bend the implant by hand during the procedure. The implant as described above can also be cut with conventional plate cutters that are routinely used for cutting titanium surgical plates or mesh.

The implant may be fixed to the bony defect with typical craniofacial screws that are sunk through the polymer portion and into the bone in lag screw fashion, sunk through one of the holes in the metal component, or sunk through a new hole drilled in the metal plate component by the surgeon. The polymer component may be designed to be pliable enough that the screw head can be driven flush with the surface of the polymer covering the metal component. The implant can also be fixed with conventional craniofacial plates and screws, where the plate overlaps the junction between the bone and the implant, and screws on the implant side are screwed through the plate hole and into the polymer portion of the implant, whereas screws on the bone side are screwed through a plate hole and into the bone.

The implant may additionally or alternatively be fixed with wires, looped through the metal in the implant and through drill holes in the bone, which is an older technique generally known to craniofacial surgeons. It could be fixed by inserting an extended metal arm from the implant edge into the cancellous space of cranial bone, with or without subsequent fixation with screws, nails or tacks. The polymer component can additionally or alternatively be sutured to the periosteum, using permanent suture. If provided, a plate extending out of the side of the implant can be bent up to the top of the

edge of the bony defect, and then over the bone at the edge of the defect and then screwed, nailed, tacked or riveted into place.

While preferred embodiments of the titanium mesh are illustrated by FIGS. 9 and 10, other titanium mesh products that can be used in connection with the invention are commercially available from sources that include Stryker Instruments, Synthes Maxillofacial, Leibinger, KLS-Martin, L. P. and Walter-Lorenz Surgical.

As seen in FIG. 14A, a defect in the cranium 178 has a floor 180 and a wall 182. This defect is typically called a split calvarial defect, where only the outer cortical surface is removed from the cranium. Split calvarial grafts are taken to repair craniofacial defects, and the resulting defect is usually under the hair and often is not repaired.

In order to address this defect, the implant may be bent to conform to the contour of the defect and cut to the shape of the defect. (It is possible to provide the implant in various sizes, which can help reduce waste and time, by reducing the amount of material that is required to be cut). The implant is placed within the defect and one side, for example, a bottom porous layer, is brought into contact with the bone on the floor and sidewalls. The implant may be secured into place with screws or sutures. Any of the embodiments of the implants described may be used for this procedure, although an implant having at least one porous surface to encourage tissue in-growth (e.g., of the bone) is particularly preferable. If an implant with one or more of the bottom surface, the top surface, and/or the sidewalls are porous, fibrovascular ingrowth into the implant is encouraged and this ingrowth serves to further stabilize the implant and diminish the possibility of rejection. It may also be preferable to use an implant that also has at least one smooth barrier surface to prevent the dermis from attaching to the outer surface of the implant.

As shown in FIG. 14B, the implant may optionally have an attachment structure or bracket 700 that extends from the implant. This bracket option is particularly useful in connection with a cranial implant designed to repair a bone defect or missing bone portion in the skull. Because the bone defect or removed bone often leaves an indentation portion 702 and because the implant cannot be secured to the exposed dura matter of other soft tissue, brackets 700 may extend from implant, either from the lower edge surface 720 of implant, the upper edge surface 722 of implant, or somewhere in between.

The brackets may be added to a completed implant or they may be formed integrally with the mesh during manufacturing. In a preferred embodiment, the brackets may have an attachment portion 704 and an angled portion 706. The attachment portion may be similar to any of the attachment portions described above. The angled portion 706 extends from the implant and allows the implant to extend down into the cavity of missing bone, and then angles up so that the implant can still be attached to the bone surrounding the cavity. If desired, the brackets 700 can be manufactured so that they are bendable (with an appropriate amount of force) and cuttable to be shortened if needed.

Fig 15 illustrates an example where a barrier was used on the top of the implant. This might may be used to help induce bony ingrowth into the underside of the porous implant, by excluding soft tissue ingrowth from the overlying tissues. The smooth barrier surface 901 on the implant allows the skin to slide over the implant area.

Another embodiment of a cranial implant is shown in FIG. 22. This implant 600 is comprised of a series of mesh bridges 602 that are connected at various angles to form variously sized inner areas 604. Mesh bridges 602 and inner areas 604 may be any appropriate size that will provide the desired strength. (This embodiment omits the annular ring structures of FIGS. 9 and 10, which can help add strength to the implant 600, although in some instances, it can lower its malleability. It should be understood, however, that annular rings may be used with cranial implants if desired.) The mesh portion is preferably covered by an upper layer and a lower layer of material, each layer of which may be a solid, non-porous barrier sheet, a porous layer, or any combination thereof. An optional layer of material may also be sandwiched between the upper and lower layers (as described above in connection with FIG. 11), in order to add thickness, support, and/or to allow the mesh to be completed enclosed by material.

As shown in FIG. 22, one embodiment of a cranial implant may have a series of one or more openings 606 that are adapted to receive a fixation structure for securing implant 600 in place. In certain embodiments, the openings may be lined with reinforcing features. They may also have a ringed portion where the upper and/or lower layer is removed to reveal a slight portion of a mesh ring 608, so that the fixation device can be countersunk into the implant 600 and not protrude above the layers.

FIG 23 shows an alternate embodiment of a cranial implant. This embodiment shows optional attachment structures 202 extending from the periphery of implant 600. As shown, the attachment structures may be a portion of the mesh 210 that has been extended past the polyolefin layer, they may be brackets 700 (as discussed above in connection with FIG. 14B), they may be ringed structures 206 (as discussed above in connection with FIG. 21), or any combination. FIG. 23 shows many options on a single implant, which is one embodiment, although another option is to provide attachment structures that are of the same type at multiple locations on a single implant.

FIG. 24 shows an example of a burr hole cover 750. During brain surgery, for example, a portion of bone may be removed by drilling four burr holes in a square or rectangle and then using a thin saw to connect the holes and remove the desired bone. Once the surgery or procedure has been competed, the removed bone may be replaced, but there are still four (or more, depending on the shape of bone removed) small empty burr holes that need to be filled. Accordingly, one embodiment of the present implant may be shaped in a generally circular configuration with various forms of any of the attachment structures 202 described herein extending from the periphery 752 of burr hole cover 750. In a particularly preferred cover 750, there are six or more attachment structures, providing the surgeon with options. The attachment structures not chosen for use, or a portion of an attachment structure (e.g., a ring) not chosen for use may be removable once the attachment structures to be used are chosen. For example, they may be clipped off, or the structures (e.g., rings) may be engaged or intertwined such that unused structures may be removed without additional instrumentation. It is also preferred that the burr hole cover 750 have a slight amount of curvature.

Various implants according to alternate embodiments of the invention may be used to cover any portion of the cranium, such as the frontal, occipital, parietal and temporal bones, portions thereof or combinations thereof. The implants may also be used to repair other bones of the face, such as the maxilla and mandible. One option is to provide implants with openings that are sized and positioned to account for various nerves and blood vessels that would otherwise be pinned beneath the implant in use, which will be described in more detail below.

In the preferred embodiments of the invention described above, the pore size of the porous polyethylene is sized large enough to allow for fibrovascular ingrowth. This pore size range would preferably be in the range of 1-1000 microns, and even more specifically, 100-250 microns, and even more specifically could vary in the range of 20-500 microns. As previously discussed, while polyethylene sheets and high density porous polyethylene matrix are preferred, it is also contemplated that other synthetic resins and combinations can be used in connection with the invention. For example PETE, PTFE and/or nylon may be selected as the thermoplastic resin. It is also should be understood that the Figures depicted herein are not necessarily drawn to scale. For example, the barrier in FIGS. 1-4 may be formed with a sheet having a much smaller width than the drawings may suggest. In a preferred embodiment the invention as depicted in FIGS. 1-4 is approximately 5 mm wide by 10 mm in length and has a thickness of approximately 1 mm. However, other dimensions are contemplated, including but not limited to 10 x 100 mm, 100 x 100 mm, 20 x 200 mm, or 5 x 5 mm.

FIG. 20 depicts an implant 500 made according to the invention in position on the orbital floor of an orbit 507. Although shown in connection with the inferior orbital floor, it should be understood that any of the embodiments of the implants described herein may be used for all aspects of the bony orbit, such as the frontal bone, the greater wing of the sphenoid bone, the zygomatic bone or arch, the maxillary bone, the lacrimal bone, and/or the ethmoid bone. The implants may also be shaped specifically for use with a particular area of the face or cranium. They can be curved, planar, or in most cases, malleable to be molded and/or twisted to the desired shape. Depending upon where the implant is to be used, it may be shaped for use with a particular area of the face or cranium. In a particular embodiment, the implants are provided in a kit of multiple implants (e.g., an orbital kit, a cranial kit, etc.) having various shapes and features to provide the surgeon with a number of alternatives depending upon the patient size and the area of the damaged bone.

The implants may further include openings (foramina), grooves, and/or channels that are intended to permit the transmission of a nerve such as the optic nerve, ophthalmic nerve or trochlear nerve, a duct such as the nasolacrimal duct, or one or more blood vessels. A channel may also be used to drain a site of excess fluid, such as blood, or

sample fluid, such as cerebrospinal fluid for analysis. In other words, providing such openings, grooves, and or channels in desired locations on various embodiments of the implant might allow the implant to be used over a nerve without causing any impingement (or crush) of the nerve when the implant is secured in place.

Another option is to provide implants that have attachment sites in various locations that are specific to the area where the implant is to be used. For example, the attachment structures 202 shown in FIG. 21 are one option, and their location and type can be varied from implant to implant. Examples of attachment sites that may be specifically designed for are certain muscle origins/insertions, tendons, artificial structures (such as a nose, an ear, and so forth).

In specific embodiments, the implants may be shaped to be thicker in some areas than others, for example, they help provide a similar appearance to both sides of the head or face due to bone loss or deterioration or more damage to one side than the other. In one instance, the polyethylene thickness could be increased for various types of implants and provided in a kit to provide the surgeon with a range of options. It may also be possible to stack implants (e.g., attach one or more implants on top of each other) to create a more even appearance to the surgical site once closed. It is also possible to provide implants of greater strength and protection, such as for the mastoid process of the temporal bone, the petrous part of the temporal bone, and so forth.

Kits may also be provided. For example, a kit with various components for a facial or a cranial kit may include the different shapes, different fastening means (e.g., screws, pins, etc.), different attachment lengths, different thicknesses, and so forth of the same item. The kit could also include aids to shaping the implant such as a clear template of the implant shape upon which the surgeon would trace the defect, cut it out of the clear plastic template, and transfer the defect shape to the implant before cutting the implant to size. The kit may optionally further include scissors for cutting the template and/or trimming the implant and instructions for the use of the implant system. Variously sized implants may also be provided.

It is further possible to provide implants having mesh with various thicknesses and patterns throughout, which allows the implant to be more malleable in some places than in others. For example, some implants may include a combination or annular ringed areas

(e.g., as shown in FIG. 9) and areas with bridges only (e.g., as shown in FIG. 22). This can impart various degrees of strength and rigidity to some areas, while imparting other degrees of malleability and moldability to other areas on the same implant. Additionally or alternatively, one portion of the implant could provide double bridges, thicker bridge, or bridges that are closer together, or any other appropriate configuration that allows varying degrees of strength and malleability.

A further optional feature is to custom-design an implant for a particular patient. A mold may be used to create a certain shape for a certain patient and the implant can be designed in a custom manner. Another option is to provide molds as a part of a kit, which would give the surgeon a general mold to initially form the implant, but then allow the surgeon to further manipulate the implant to fit the patient being treated.

Another optional feature that any of the implants described herein may have is to be seeded with the autologous or heterologous cells (e.g., stem cells, osteoblasts, fibroblasts). Biologically active molecules such as growth factors, hormones, antibiotics, and/or with any other biological substance may be applied to the implant in order to either help prevent rejection of the implant, prevent infection, facilitate cellular growth into the implant, help stimulate capillary formation, osteogenesis, and so forth. The cells or hormones or other substance may be applied topically to the implant prior to implantation, the implant could be soaked in a solution containing the biologically active molecule and or cells, the material could be sprayed on or applied by syringe, the material may be dissolved in a slow release resorbable polymer which is then formed into the pores of the implant, or applied by using any other appropriate application method.

In addition to the repair and reconstruction of orbital defects, the implants according to the invention may be advantageously employed with other surgery such as the repair of lost bone flaps resulting from neurological procedures, repair of the mastoid area after a mastoidectomy, fixation for LeFort procedures, or fixation for sliding genioplasty. It is further contemplated that the planar sheets may be bent into tubular shapes and used for orthopedic applications. A planar sheet bent in a U shaped configuration may be useful in connection with spinal fixation procedures or the repair of herniated disks.

The following application is related to the current application and is hereby incorporated by reference: U.S. Application Serial No. 11/445,560 titled "Craniofacial Implant" filed on June 2, 2006, which is a continuation-in part of U.S. Application Serial No. 10/517,843 titled "Craniofacial Implant" filed on July 12, 2005. Any other patents, publications and abstracts cited above are incorporated herein by reference in their entirety.

The invention having been described in detail with respect to preferred embodiments above, it will now be apparent from the foregoing to those skilled in the art that changes and modifications may be made without departing from the invention in its broader aspects, and the invention, therefore, as defined in the appended claims is intended to cover all such changes and modifications as fall within the true spirit of the invention.

What is claimed is:

1. A composite surgical implant comprising

(a) a top surface and a bottom surface, each surface comprising a layer of a polyolefin material,

(b) a surgical grade metal mesh contained between the top and bottom surfaces, and

(c) one or more attachment structures adapted to attach the implant to a desired surface,

the implant being bendable or displaceable by manipulation by hand, wherein upon the displacement of the implant, the implant will generally maintain the shape to which it has been displaced.

2. The implant of claim 1, wherein the surgical grade metal mesh comprises titanium, surgical grade stainless steel, steel coated with titanium, titanium nitride, titanium alloyed with other metals, composites of any of the above materials, or any combination thereof.

3. The implant of claims 1 or 2, wherein polyolefin material comprises polyethylene, high density polyethylene, ultra high molecular weight polyethylene, polyether ether ketone, thermoplastic resins, polyethylene terephthalate, nylon, any polymer of aliphatic hydrocarbons containing one or more double bonds, composites of any of the above materials, or any combination thereof.

4. The implant of claim 1, wherein the top surface, the bottom surface, or both surfaces comprise a smooth barrier surface.

5. The implant of claim 1, wherein the top surface, the bottom surface, or both surfaces comprise a porous surface.

6. The implant recited in claim 5, wherein pores of the porous surface are sized to allow for fibrovascular ingrowth.

7. The implant recited in claim 5, wherein pore sizes range from about 1 to about 1000 microns.

8. The implant of claim 1, wherein one of the top or bottom surface comprises a smooth barrier surface and the other of the top or bottom surfaces comprises a porous surface.

9. The implant of any of the preceding claims, wherein the one or more attachment structures comprise openings in the mesh that will receive and engage a head of a surgical screw or surgical bone anchor.

10. The implant of any of the preceding claims, wherein the one or more attachment structures comprise one or more strands of rings that are adapted to receive a fixation device.

11. The implant of claim 1, wherein the one or more attachment structures are attached to the implant at one or more locations where the implant will be secured to bone.

12. The implant of claim 1, wherein the one or more attachment structures comprise one or more angled brackets.

13. The implant of any of the preceding claims, wherein the implant is provided in a particular shape to approximately fit a particular surgical site.

14. The implant of any of the preceding claims, wherein the implant further comprises cells or biologically active molecules.

15. The implant of any of the preceding claims, wherein the implant comprises openings, grooves, or channels that are adapted to accommodate nerves or vessels that may lie underneath the implant during use.

16. The implant of any of the preceding claims, wherein the implant is provided in a kit of implants having varied features.

17. The implant of claim 16, wherein the varied features comprise one or more of varied thicknesses, mesh patterns, strengths, sizes, shapes, malleability, seeding options, or combinations thereof.

18. The implant of any of the preceding claims, wherein the metal mesh is sized to allow load bearing reconstructions of the mandible or long bones, and the polyolefin material provides volume filling capacity for resected or deficient bony structures, and provides a smooth surface over the metal component to minimize the possibility of implant exposure through the skin or soft tissues.

19. The implant of any of the preceding claims, wherein the surgical grade metal mesh comprises wire screen, expanded metal, perforated metal sheet, perforated bars, an interconnected meshwork of perforated bars, a grid, a free form solid, a perforated or machined shaped sheet, or any combination thereof.

20. A method of making a surgical implant comprising:
    (a) placing a metallic mesh material having a body portion and an attachment structure portion over a cavity in a lower portion of a mold, such that the attachment structure portion rests on a ledge; and
    (b) introducing thermoplastic resin fines into the cavity portion of the mold to allow the fines to fill the lower portion of the mold and the interstitial spaces of the body portion of the mesh.

21. The method of claim 20, further comprising:
    (c) placing a sheet of thermoplastic resin over the fines and the mesh;
    (d) placing a mold top over the sheet and applying heat and pressure to the components contained in the mold to allow the fines to partially melt and to fuse to one another,

whereby an implant is constructed having a smooth barrier surface and an opposite porous surface.

22. The method of claim 20, wherein (a) comprises placing a thin barrier sheet on the bottom surface of a cavity of the mold, whereby the implant created comprises barriers on opposite sides of the mesh.

23. The method of claim 21, wherein the fines are allowed to extend into an upper portion of the mold having a second cavity, in order to cover both sides of the body portion.

24. A method of reconstruction of a bone defect comprising,

(a) bending a surgical implant having a top and bottom surface comprised of a polyolefin material, a metallic mesh embedded in the material to conform to the profile of the defect, and one or more attachment structures extending from the implant; and,

(b) mechanically attaching the implant to bone in proximity with the defect using the attachment structures that extend from the implant.

25. The method of reconstruction recited in claim 24, wherein the defect is in the cranium.

26. The method of reconstruction recited in claim 24, wherein the defect is in the orbit.

27. The method of reconstruction recited in claims 24 or 25, wherein the implant further comprises a top smooth barrier surface and a bottom porous surface and the implant is positioned over a cranial defect with the top smooth barrier surface oriented away from the defect.

28. The method of reconstruction recited in claims 24 or 26, wherein the implant further comprises a top smooth barrier surface and a bottom porous surface and the implant is

positioned in the orbit with the top smooth barrier surface oriented toward the orbital defect.

29. The method of reconstruction as recited in claims 24-26, wherein the attaching step comprises introduction of mechanical fasteners through the attachment structures and into the bone.

30. The method of reconstruction as recited in claim 29, wherein the mechanical fasteners comprise surgical screws.

31. The method of reconstruction recited in claim 24, further comprising cutting the implant to conform to the shape of the defect.

32. A kit for the repair of a bone defect, comprising

(a) one or more surgical implants comprising a top surface and a bottom surface, each surface comprising a layer of a polyolefin material and a surgical grade metal mesh contained between the top and bottom surfaces, the surgical implant further comprising one or more attachment structures adapted to attach the implant to a desired surface, the implant being bendable or displaceable by manipulation by hand; and

(b) one or more aids for shaping the implant.

33. The kit of claim 32, wherein the surgical implants are provided in one or more different sizes, shapes, or thicknesses and/or having one or more different attachment structures.

34. The kit of claims 32 or 33, wherein the one or more aids for shaping the implant comprises a clear template of the implant shape.

35. The kit of any of claims 32 or 33, further comprising one or more of:

(c) scissors for cutting the template or trimming the implant;

(d) instructions for the use of the implant; or

(e) both (c) and (d).

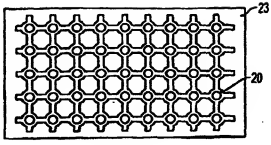

FIG. 1

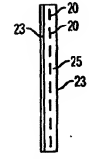

FIG. 2

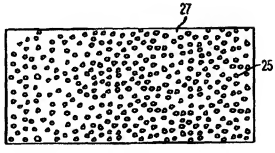

FIG. 3

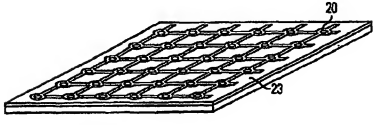

FIG. 4

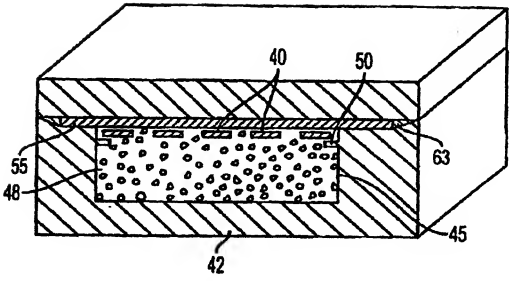

FIG. 5

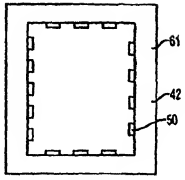

FIG. 6

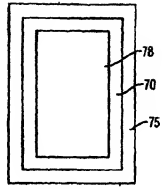

FIG. 7

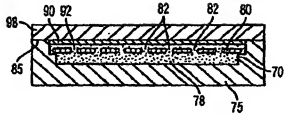

FIG. 8

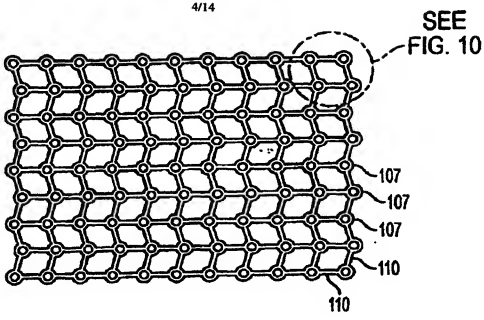

FIG. 9

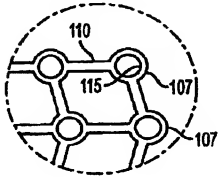

FIG. 10

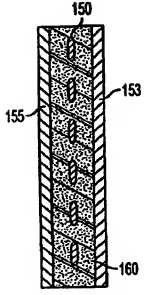

FIG. 11

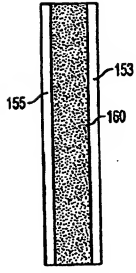

FIG. 12

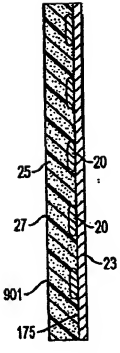

FIG. 13

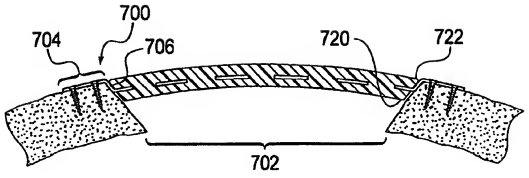

FIG 14A

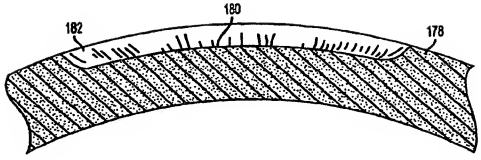

FIG. 14B

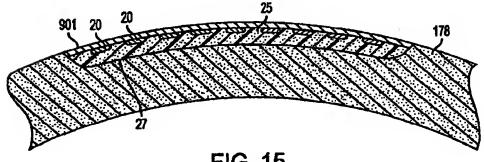

FIG. 15

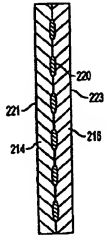

FIG. 16

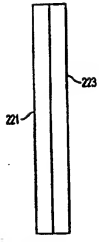

FIG. 17

FIG. 18

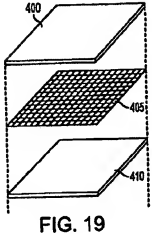

FIG. 19

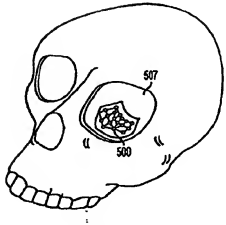

FIG. 20

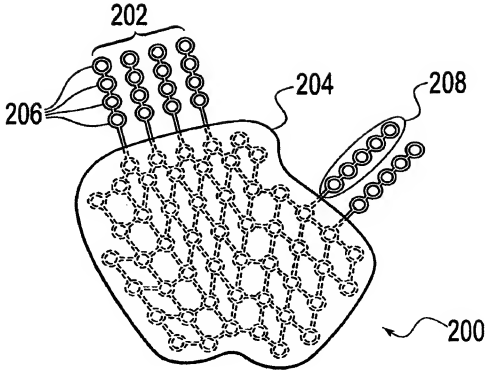

FIG. 21

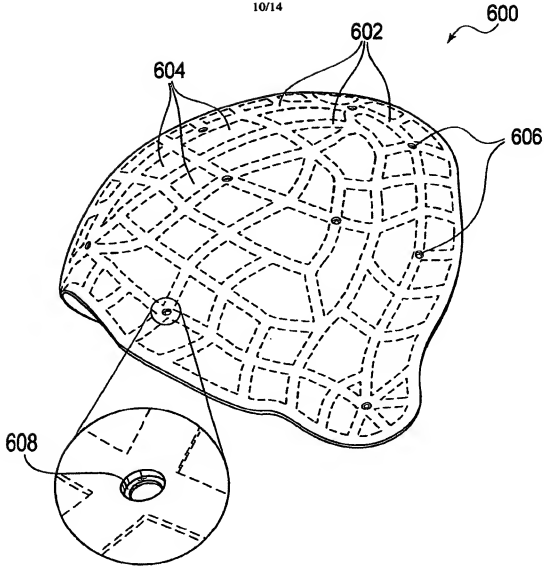

FIG. 22

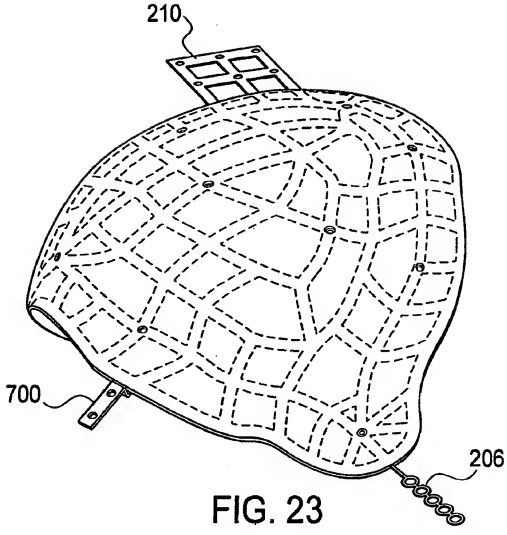

FIG. 23

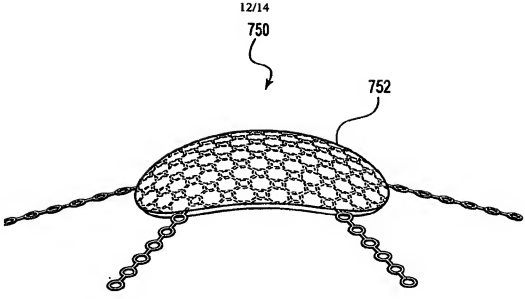

FIG. 24

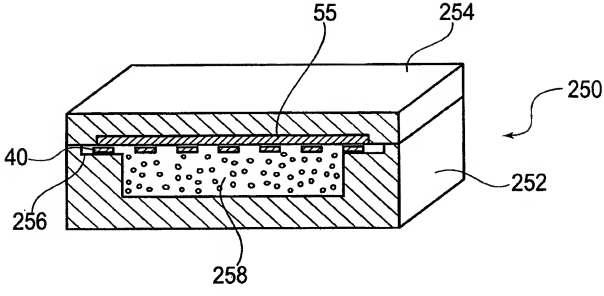

FIG. 25

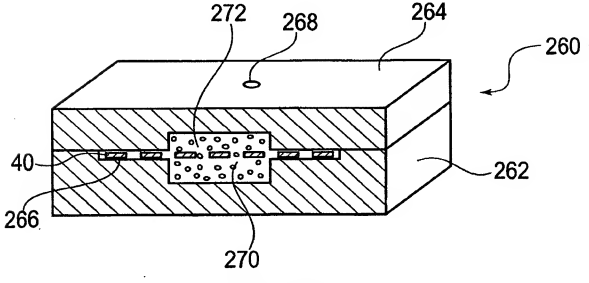

FIG. 26

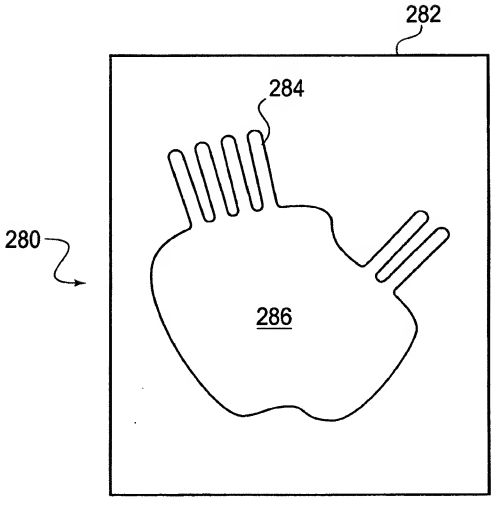

FIG. 27

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/009471

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/28 A61L27/44 A61L27/56 A61B17/80 A61F2/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61L A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/093743 A (POREX SURGICAL INC [US]; SWORDS GREG [US]) 4 November 2004 (2004-11-04) claims 1-21	1,3-14, 16-35
X	US 5 380 328 A (MORGAN FRANK H [US]) 10 January 1995 (1995-01-10) claims 1-16	1,2,6,15
A	JANECKA IP: "New reconstructive technologies in skull base surgery" ARCHIVES OF OTOLARYNGOLOGY HEAD AND NECK SURGERY, vol. 126, 2000, pages 396-401, XP002488370 the whole document	1-35
A	US 2006/116682 A1 (LONGO MARC N [US]) 1 June 2006 (2006-06-01) claims 1-18	1-35

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 July 2008	08/08/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schneider, Aurore

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/009471

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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			CN	1777400 A	24-05-2006
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			KR	20060033858 A	20-04-2006
			US	2005288790 A1	29-12-2005
US 5380328	A	10-01-1995	NONE		
US 2006116682	A1	01-06-2006	NONE		